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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,422	10/06/2005	Roland W. Burli	020891-001411US	1167

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EXAMINER
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BARKER, MICHAEL P

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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01/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/523,422

Applicant(s)

BURLI ET AL.

Examiner

Michael P. Barker

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/06/2005, FILING DATE.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 is/are allowed.
- 6) ☒ Claim(s) 1,2,7,9 and 12-16 is/are rejected.
- 7) ☒ Claim(s) 2-9 and 11-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/12/06; 4/3/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

**Claims 1-16** are pending in this Application.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 10/12/2006 and 04/03/2006 were correctly filed. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS's were considered by the Examiner. Please refer to Applicant's copies of PTO-1449, submitted herewith.

### ***Claim Rejections - 35 USC § 112 ¶1***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1, 2, 7, 9, and 12** rejected under 35 USC 112 ¶1 paragraph as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it

obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

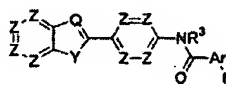
Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

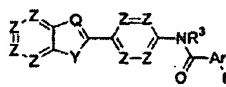
“A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...”) *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

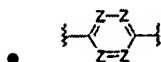
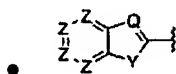
The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what does not constitute a representative number of species to adequately describe a broad genus. For example, in *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pg. 1105, column 3), in accordance with MPEP § 2163, specifically state that for each claim drawn to a genus, the written description requirement may be satisfied through a sufficient description of a representative number of species by a) actual reduction to practice; b) reduction to drawings or structural chemical formulas; c) disclosure of relevant, identifying characteristics (i.e. structure) by functional characteristics coupled with a known or disclosed correlation between function and structure. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention (Federal Register, Vol. 66, No. 4, p. 1105, 3<sup>rd</sup> column, 3<sup>rd</sup> paragraph).

### Scope of Claims



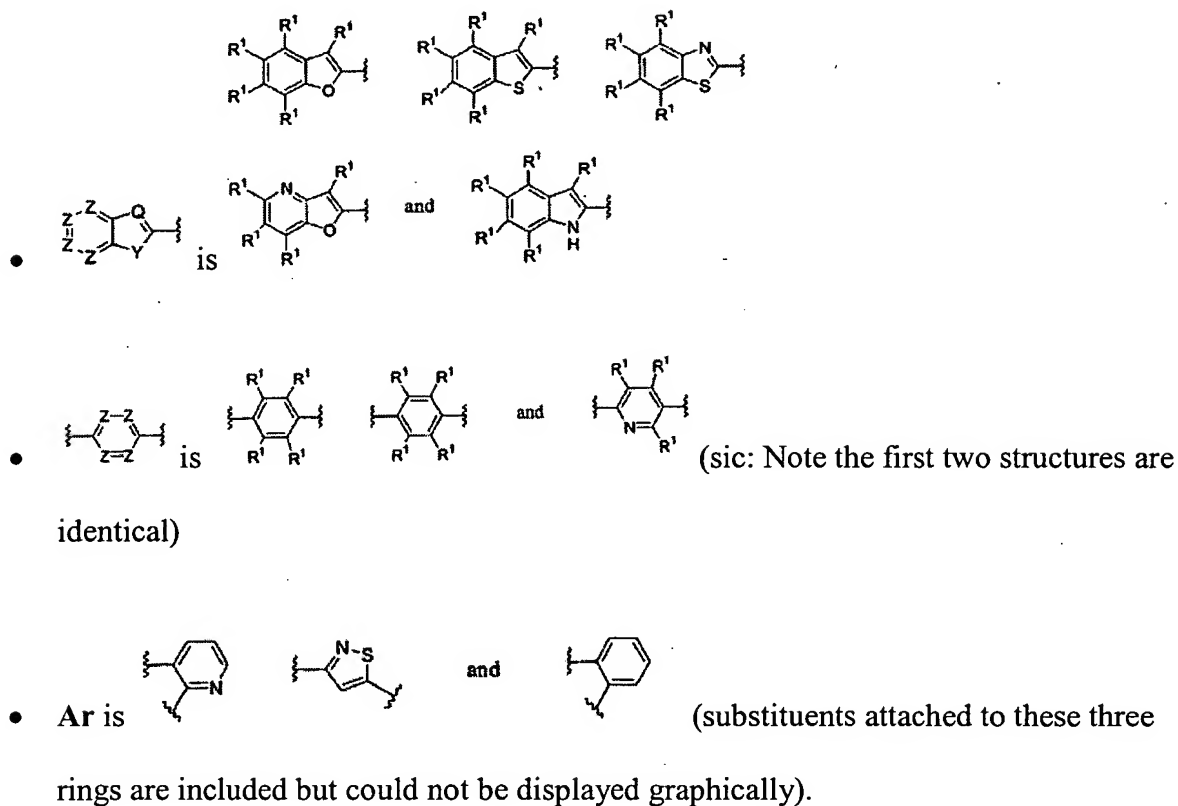
Compounds of the general formula, . The following moieties are claimed broadly than what is supported by the scope of the disclosure:



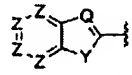
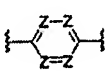
Scope of Disclosure

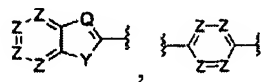
Reduction to Practice:

The compounds reduced to practice support the following definitions of the  
aforementioned moieties:



Reduction to Structural or Chemical Formulas:

The only disclosure, in addition to the species reduced to practice, is in form of a  
list or “genus” (e.g. , , and Ar) of possible substituents for the moieties. This  
type of disclosure is not viewed to be sufficient to claim every of structure encompassed by



, and Ar. A “laundry list” disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not “reasonably lead” those skilled in the art to any particular species. MPEP 2163.I.A. and *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Therefore, there is no disclosure of species (e.g. by reduction to structural/chemical formulas) in addition to those reduced to practice, listed above.

Correlation between Structure and Function:

Structure-activity studies are disclosed in the art for anti-bacterial/anti-fungal compounds and compositions for genres of compounds different from those instantly claimed. Although these studies do not address the activity of the compounds of the instant genus as a function of structural modifications, they do show that a compound’s ability to treat bacteria and fungi is influenced by structural changes to the common chemical core. Because the instant specification does not disclose any correlation between function and structure, and because such correlation does not exist in the art for the instantly claimed genus of compounds, one of ordinary skill would not know what *specific structural elements* are *essential* for the activity of the instantly claimed compounds.

Analysis of Fulfillment of Written Description Requirement:

In the absence of a correlation between structure and function, it is not possible to know what modifications to the instantly claimed core structure will allow for the preservation of the

desired activity. For example, one of ordinary skill cannot predict whether the activity will be preserved upon changing the aforementioned moieties to result in a compound unrepresented by the instant disclosure.

In conclusion: (i) substantial structural variation exists in the genus/subgenus embraced by **Claims 1, 2, 7, 9, and 12**; (ii) disclosure of species supporting genus is limited to compounds reduced to practice, which scope is not commensurate with the scope of genus/subgenus claimed; and (iii) common structural attributes of the claimed genus/subgenus, combined with a correlation between structure and function, is neither disclosed in the instant application nor commonly known in the art. Thus, the specification fails to provide adequate written description for the genus of compounds claimed and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

***Claim Rejections - 35 USC § 112 ¶1***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 13-15** are rejected under 35 U.S.C. § 112, first paragraph, because the Specification, while enabling for (1) treating gram-positive bacterial infections, does not reasonably provide enablement for every bacterial infection in a mammal (namely, gram-negative bacterial infections). Therefore, the Specification does not enable any person skilled in



the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'."

*In re Wands*, 8 USPQ2d 1400 (1988), discusses the following factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph:

1. *The nature of the invention;*
2. *The state of the prior art;*
3. *The predictability or lack thereof in the art;*
4. *The amount of direction or guidance present;*
5. *The presence or absence of working examples;*
6. *The breadth of the claims;*
7. *The quantity of experimentation needed; and*
8. *The level of skill in the art*

#### ***The nature of the invention***

**Claim 13** is drawn to a method of treating any bacterial infection in a mammal.

**Claims 14 and 15** narrow the scope of Claim 13 to various drug resistant bacterial infections.

#### ***The state of the prior art and the predictability or lack thereof in the art***

The state of the prior art, namely pharmacology, involves screening *in vitro* and *in vivo* to determine if the compounds exhibit desired pharmacological activities, which are then tested for their efficacy on human beings. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the

contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instantly claimed invention is unpredictable in terms of the nonenabled subject matter of **Claims 13-15**.

As stated, pharmacology is an unpredictable art, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly complex, and one skilled in the art may recognize the claimed compounds as anti-bacterial in respect to gram-positive bacteria (either directly or peripherally within the mechanism of action) in assays. However, such properties do not mean that the same group of compounds and compositions may treat every type of bacterial infection.

The state of the prior art is silent as to whether Applicant's claimed genus of compounds is capable of treating both gram-positive and gram-negative bacterial infections.

***The amount of direction or guidance present and the presence or absence of working examples***

There is no direction or guidance presented which substantiates Applicant's claimed compounds as capable of treating every type of bacterial infection. The direction or guidance presented in Applicants' Specification provides evidence that establishes the claimed compounds as capable of ameliorating gram-positive bacterial infections. No *in vivo* data has been provided to support the scope of the instant claims.

***The breadth of the claims, quantity of experimentation, and level of skill in the art***

**Claims 13-15** encompass treating every bacterial infection. In order to treat a disease, one would need to demonstrate what the subject population is, what the necessary dose is for efficacy, and that the subject has recovered from such a disease.

Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success.

***Claim Rejections - 35 USC § 112/101***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 16** provides for the “use of a compound according to claim 1, 2, or 8 for the preparation of a medicament. . .”, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claim 16** is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Allowable Subject Matter***

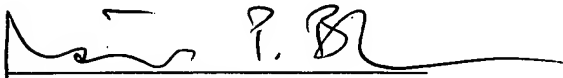
**Claim 10** is drawn to allowable subject matter.

***Objections***

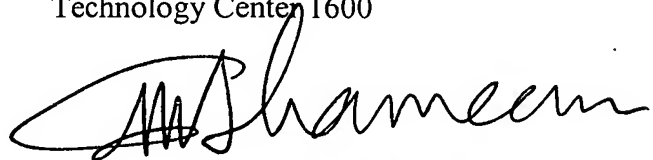
**Claims 2-9, and 11-16** depend from a rejected base claim.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

  
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PRIMARY EXAMINER